



**Department of Veterans Affairs  
Jesse Brown VA Medical Center  
820 S. Damen Avenue  
Chicago, IL. 60612**

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Version 1.2

**Reporting Research Events to  
Facility Oversight Committees  
and Office of Research  
Oversight (ORO)**

**PURPOSE**

The purpose of this SOP is to describe reporting procedures of research events to JBVAMC research oversight committees and Office of Research Oversight (ORO).

**POLICY**

Reporting of research events policy must follow VHA handbook 1058.01 of reporting to Jesse Brown VAMC oversight committees and ORO.

**BACKGROUND**

ORO serves as the primary VHA office for advising the Under Secretary for Health and exercising oversight concerning all matters of research compliance and assurance, including human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, research misconduct, debarment for research impropriety, and other matters that the Under Secretary for Health may assign. ORO is responsible for developing and conducting research compliance officer education programs as directed by the Under Secretary for Health.

**SCOPE**

The scope of VHA handbook 1058.01 is to:

1. identifies the research events that must be reported to Jesse Brown VAMC research oversight committees, ACOS/R&D, and Medical Center Director,
2. identifies the research events that must be reported to ORO Regional Offices (Midwestern),

3. identifies the research events that must be reported to ORO Central Office,
4. provides the methods and timelines for reporting such events, and
5. indicates what information must be provided in reports of these events.

#### **A. REPORTING EVENTS RELATED TO HUMAN RESEARCH TO ORO**

1. Refer to the following UIC HSPP policies and procedures for reporting requirements for the investigator, IRB, RCO, ACOS/R&D, and R&D Office:
  - *Unanticipated Problems and Other Events Requiring Prompt Reporting,*
  - *Administrative Hold, Suspension or Termination of IRB Approval,*
  - *Handling Complaints and Allegations of Potential Non-Compliance with Human Subject Protection Regulations,*
  - *Reporting of Unanticipated Problems, Suspensions, Terminations, and Non-Compliance,*
  - *Reporting of Complaints and Allegations of Non-Compliance to the Collaborative JBVAMC/NU/UIC IRB (IRB #4) from the JBVAMC and Northwestern University Performance Sites, and*
  - *Operating and Coordinating Procedures for the Administration of the Collaborative JBVAMC/NU/UIC IRB (IRB #4).*
2. In addition, the Medical Center Director must report the following research events to ORO Central Office, with a simultaneous copy to the ORO Regional Office (Midwestern), as indicated below:
  - a. **Assurance Changes.** Proposed changes to the JBVAMC's Federal-wide Assurance (FWA), or other human research Assurance, must be submitted to ORO Central Office prior to submission to OHRP and in accordance with VHA Handbook 1058.03.
  - b. **IRB Changes.** The proposed addition or removal of the IRBs of record designated the JBVAMC's FWA must be submitted to ORO Central Office prior to submission to OHRP and in accordance with VHA Handbook 1058.03. Any change in IRB membership rosters must be reported to ORO Central Office in accordance with VHA Handbook 1058.03.
  - c. **Substantive MOU Changes.** Any substantive change in an MOU with an affiliate institution or other entity related to the designation of IRB(s) or other human research protection arrangements must be reported to ORO Central Office within 5 business days.
  - d. **Accreditation Problems.** Failure of the JBVAMC to achieve the accreditation status required by ORD for human research protections, any change in the JBVAMC's accreditation status, or any change in the accreditation status of an affiliate involved in the JBVAMC's human research protection program must be reported to ORO Central Office within 5 working days.

#### **B. REPORTING RESEARCH EVENTS RELATED TO ANIMAL RESEARCH TO ORO**

1. Investigators, RCOs, and other members of the VA research community must report the research events subparagraphs 8 a, 8 b, 8c, and 8d VHA Handbook 1058.01 in writing to the IACUC as soon as possible, but **no later than 5 business days** after becoming aware of them.
  - a. If the RCO identifies serious or continuing noncompliance during a regulatory audit, he/she must report the noncompliance to the Medical Center Director, the ACOS/R&D, the R&D Committee, and the IACUC as soon as possible, but **no later than 5 business days** after becoming aware of them.
2. **IACUC Review of Reported Incidents.** The IACUC must review any report involving an apparent incident or event as described at subparagraphs 8 a through 8d VHA Handbook 1058.01 at its next convened meeting. *[If the significance of a reported event is not clear, the IACUC Chair, or designee, is to consult the ORO RO and the ORO Associate Director for Research Safety and Animal Welfare. Questions about reporting to OLAW or other Federal agencies must be referred directly to the relevant agency or to the ORO Associate Director for Research Safety and Animal Welfare who will confer with the ORD Chief Veterinary Medical Officer (VMO) as appropriate.]*
  - a. Incidents that present a significant risk to the safety of research personnel, animals, or the environment may require immediate attention and result in the need to convene an emergency session of the IACUC prior to the next scheduled meeting.
  - b. Should the IACUC determine that a reportable incident or event as described at subparagraphs 8a through 8d occurred, the IACUC Chair, or designee must report the determination directly (without intermediaries) to the Medical Center Director **no later than 5 business days** after the IACUC's determination.
  - c. The report must be made in writing, with a simultaneous copy to the ACOS/R&D, the R&D Committee, and any other relevant research review committee.
  - d. The Medical Center Director must report the IACUC's determination (i.e., that a reportable incident or event occurred) to the ORO RO (Midwestern), with a simultaneous copy to the VISN Director and the ORD, **no later than 5 business days** after receiving such notification.
  - e. An initial report of an IACUC determination is required regardless of whether the determination is preliminary and still under investigation or final disposition of the matter has been resolved at the time of the report. *[The IACUC must reach a determination that a reportable event did (or did not) occur within 30-45 days after receiving a relevant report. According to subparagraph 5d of VHA Handbook 1058.01, remedial actions involving a specific study or research team must be completed within 90-120 days after the IACUC's determination. Remedial actions involving programmatic noncompliance must be completed within 120-180 days after the IACUC's determination, unless remediation requires substantial renovation, fiscal expenditure, legal negotiation, etc. Where it is known at the outset that completion of remedial actions will extend beyond these periods, for*

*example where significant infrastructure improvements or major equipment purchases are needed, the ORO RO (Midwestern) must be consulted regarding development of an acceptable plan to minimize negative impact on animal welfare or critical research activities.]*

- f. There is **no 5 business day** requirement to report noncompliance to the ORO RO (Midwestern) or to the ORO Central Office. The noncompliance must be reported to these agencies if the IACUC committee reviews and makes a final determination of noncompliance.
3. **Suspensions or Terminations of Animal Research:** Any suspension or termination of research (e.g., by the IACUC or other research review committee, or by the ACOS/R&D, or other facility official) related to concerns about the safety, health, or welfare of laboratory animals or the safety, rights, or welfare of research staff or others, or due to operational problems that necessitate a voluntary or involuntary interruption in the conduct of animal research, must be reported directly (without intermediaries) to the Medical Center Director **no later than 5 business days** after the suspension or termination occurs.
- a. The report must be made in writing with simultaneous copies, as applicable, to the ACOS/R&D, the R&D Committee, the IACUC, and any other relevant research review committee.
  - b. The Medical Center Director must report the termination or suspension to the ORO RO (Midwestern) **no later than 5 business days** after receiving such notification.
  - c. Suspensions or terminations of animal research are to be reported whether they impact a specific study or the entire program.
  - d. Operational problems that must be reported when they necessitate interruption in the conduct of animal research include the unanticipated resignation of an individual essential to the program (e.g., VMO or Veterinary Medical Unit Supervisor) or physical plant issues that must be addressed to remain in compliance with VA or other Federal requirements.
4. **Reports to ORO Regional Office:** Based on the information above, and as indicated in VHA Handbook 1058.01, the Medical Center Director must report the following research events to the ORO RO (Midwestern) as soon as possible, but **no later than 5 business days** after being informed of them. These items are also summarized in App. A, Table 1 and Flow Chart 1.
- a. **Unanticipated Loss of Life** (subparagraph 8a VHA Handbook 1058.01)
  - b. **Animal Theft or Potentially Dangerous Escape** (subparagraph 8b VHA Handbook 1058.01)
  - c. **Work-Related and Other Injuries** (subparagraph 8c VHA Handbook 1058.01)
  - d. **Reportable Incidents Under Applicable Federal Standards** (subparagraph 8d VHA Handbook 1058.01)
    1. This includes but is not limited to serious or continuing noncompliance. Any findings of noncompliance related to animal research by any VA office, any other federal department or agency (e.g., the United States Department of Agriculture), or any other

entity must be reported. The Medical Center Director's report to ORO must include a copy of the entity's official findings.

e. **Suspensions or Terminations.** (subparagraph 8f VHA Handbook 1058.01)

5. **Reports to ORO Central Office:** The Medical Center Director must report the following research events to ORO Central Office, with a copy to the appropriate ORO RO (Midwestern), as soon as possible, but no later than 5 business days after being informed of them. These items are also summarized in App. A, Table 2; Flow Chart 2.

a. **Assurance Changes.** Any change in the JBVAMC's Animal Welfare Assurance status as filed with the PHS Office of Laboratory Animal Welfare (OLAW), or in the Animal Welfare Assurance status of an affiliate institution or other entity upon which the facility relies, must be reported. Simple Assurance renewals, without changes in status, need not be reported.

b. **New MOU or Substantive MOU Changes.** The implementation of any new MOU, or any substantive change in an existing MOU, with an affiliate institution (or other entity) related to laboratory animal welfare or animal care and use arrangements.

c. **Accreditation Problems.** Failure of the JBVAMC to achieve the accreditation status required by ORD for animal care and use programs, any change in the JBVAMC's accreditation status, or any change in the accreditation status of an affiliate involved in the facility's animal care and use program, must be reported.

### C. REPORTING RESEARCH EVENTS RELATED TO RESEARCH SAFETY TO ORO

1. Investigators, RCOs, and other members of the VA research community must report the events listed in subparagraphs 9 a, 9 b, and 9c VHA Handbook 1058.01 in writing to the Subcommittee on Research Safety (SRS) as soon as possible, but **no later than 5 business days** after becoming aware of them.

a. If the RCO identifies serious or continuing noncompliance during a regulatory audit, he/she must report the noncompliance to the Medical Center Director, the ACOS/R&D, the R&D Committee, and the SRS as soon as possible, but **no later than 5 business days** after becoming aware of them.

2. **SRS Review of Reported Events.** The SRS must review at its next convened meeting any report involving an incident or event described at subparagraphs 9a through 9c VHA Handbook 1058.01. *[If the significance of a reported event is not clear, the SRS Chair, or designee, must consult the ORO RO and the ORO Associate Director for Research Safety and Animal Welfare.]*

a. Incidents that present a significant risk to the safety of research personnel or the environment may require immediate attention and result in the need to convene an emergency session of the SRS prior to the next scheduled meeting.

- b. Should the SRS determine that a reportable incident or event as described at subparagraphs 9a through 9c VHA Handbook 1058.01 occurred, the SRS Chair must report the determination directly (without intermediaries) to the Medical Center Director **no later than 5 business days** after the SRS's determination.
  1. The report must be made in writing, with a simultaneous copy to the ACOS/R&D, the R&D Committee, and any other relevant research review committee.
  2. The Medical Center Director must report the SRS's determination (i.e., that a reportable incident or event occurred) to the ORO RO (Midwestern), with a simultaneous copy to the VISN Director and the ORD **no later than 5 business days** after receiving such notification.
  3. An initial report of an SRS determination is required regardless of whether the determination is preliminary and still under review or final disposition of the matter has been resolved at the time of the report. *[ The SRS must reach a determination that a reportable event did (or did not) occur within 30-45 days after receiving a relevant report. According to subparagraph 5d VHA Handbook 1058.01, remedial actions involving a specific study or research team must be completed within 90-120 days of the SRS's determination. Remedial actions involving programmatic noncompliance must be completed within 120-180 days after the SRS's determination, unless remediation requires substantial renovation, fiscal expenditure, legal negotiation, etc.]*
  4. There is **no 5 business day** requirement to report noncompliance to the ORO RO (Midwestern) or to the ORO Central Office. The noncompliance must be reported to these agencies if the SRS committee reviews and makes a final determination of non-compliance.
3. **Suspensions or Terminations.** Any suspension or termination of research (e.g., by the SRS or other research review committee, or by the ACOS/R&D or other facility official) related to concerns about research safety must be reported directly (without intermediaries) to the Medical Center Director **no later than 5 business days** after the suspension or termination occurs.
  - a. The report must be made in writing with simultaneous copies, as applicable, to the ACOS/R&D, R&D Committee, the SRS, and any other relevant research review committee.
  - b. The Medical Center Director must report such suspension or termination of research to the ORO RO (Midwestern) **no later than 5 business days** after being notified.
4. **Laboratory Decommissions.** The PI or Laboratory Director must obtain authorization (i.e., permission) from the SRS and the ACOS/R&D prior to reassigning, vacating, converting to non-laboratory use, or otherwise decommissioning existing laboratory space that requires identification and disposal of hazardous materials, infectious agents, or equipment between uses.

- a. The request for authorization to decommission laboratory space must be made in writing at least 1 month prior to implementation. Upon receiving such a request, the ACOS/R&D must notify the VISN Safety Office to coordinate inventory and removal of hazardous materials, infectious agents, or equipment.
- b. Within 5 business days of discovering, receiving a credible report of, or otherwise becoming aware of any decommissioning implemented without the required authorization, the ACOS/R&D must report the incident directly (without intermediaries) to the Medical Director and the VISN Safety Office.
- c. The Medical Center Director must report any unauthorized decommissioning to the ORO RO (Midwestern) **no later than 5 business days** after being notified.

**5. Reports to ORO Regional Office:** Based on the information above, and as indicated in VHA Handbook 1058.01, the Medical Center Director must report the following research events to the ORO RO (Midwestern) as soon as possible, but **no later than 5 business days** after being informed of them. These items are also summarized in App. A, Table 1 and Flow Chart 1.

- a. **Work-Related or Research-Related Injuries** (subparagraph 9a VHA Handbook 1058.01)
- b. **Work-Related Exposures or Injuries** (subparagraph 9b VHA Handbook 1058.01)
- c. **Reportable Incidents Under Applicable Federal Standards** (subparagraph 9c VHA Handbook 1058.01)
  - 1. This includes but is not limited to serious or continuing noncompliance. Any findings of noncompliance related to research safety by any VA office, any other Federal department or agency (e.g., United States Environmental Protection Agency), or any other entity (e.g., State Environmental Protection Agency). The Medical Center Director's report to ORO must include a copy of the entity's official findings.
- d. **Suspensions or Terminations.** (subparagraph 9e VHA Handbook 1058.01)
- e. **Laboratory Decommissions** (subparagraph 9f VHA Handbook 1058.01)

**6. Reports to ORO Central Office.** As soon as possible but **no later than 5 business days** after being informed of any substantive change in an MOU with an affiliate institution (or other entity) related to research safety arrangements, the Medical Center Director must report the change to ORO Central Office, with a simultaneous copy to the ORO RO (Midwestern). This is also summarized in App. A, Table 2 and Flow Chart 2.

**D. REPORTING RESEARCH EVENTS RELATED TO RESEARCH LABORATORY SECURITY TO ORO**

- 1. Investigators, RCOs, and other members of the VA research community must report the events listed in subparagraphs 10a(1), 10a(2), 10a(3), and 10a(4) VHA

Handbook 1058.01 in writing to the ACOS/R&D as soon as possible, but **no later than 5 business days** after becoming aware of them.

- a. If the RCO identifies serious or continuing noncompliance during a regulatory audit, he/she must report the noncompliance to the Medical Center Director, the ACOS/R&D, and the R&D Committee as soon as possible, but **no later than 5 business days** after becoming aware of them.
2. **Reports to the Medical Center Director and ORO ROs. No later than 5 business days** of discovering, receiving a credible report of, or otherwise becoming aware of any situation described at subparagraph 10a VHA Handbook 1058.01, the ACOS/R&D must report the incident directly (without intermediaries) to the Medical Center Director.
  - a. The report must be made in writing with simultaneous copies to the R&D Committee, any relevant research review committee, and the VA Police Service.
  - b. **No later than 5 business days** of being notified of them, the Medical Center Director must report the research laboratory security incidents listed in subparagraph 10a VHA Handbook 1058.01 to the ORO RO (Midwestern).
3. **Reports to ORO Regional Office: Based on the information above, and as indicated in VHA Handbook 1058.01, the Medical Center Director must report the following research events to the ORO RO (Midwestern) as soon as possible, but no later than 5 business days** after being informed of them. These items are also summarized in App. A, Table 1.
  - a. **Physical Security Problems** (subparagraph 10a(1) VHA Handbook 1058.01)
    1. This includes any break-in, physical security breach, or other physical security problem affecting VA research that involves any of following:
      - a. Injury or harm to a human individual or laboratory animal
      - b. A Biosafety Level 3 (BSL-3) research laboratory.
      - c. Loss of any quantity of a select agent or toxin.
      - d. Loss of any quantity of a highly hazardous agent. [*For VA research, highly hazardous agents include select agents or toxins; agents, toxins, or other biological materials requiring handling at BSL-3 or higher containment; highly toxic chemicals and gases that have the potential for readily causing widespread harm if misused; and high risk radioactive materials and/or radiation sources.*]
      - e. Substantial damage to the facility.
      - f. Substantial loss of equipment, physical resources, or research animals. [*Loss of any equipment that holds electronic data or documents must be reported in accordance with paragraph 10 below.*]
  - b. **Findings of Noncompliance** (subparagraph 10a(2) VHA Handbook 1058.01)

1. Any findings of noncompliance related to research laboratory security by any VA office, any other Federal department or agency (e.g., Department of Homeland Security), or any other entity. The Medical Center Director's report to ORO must include a copy of the entity's official findings.
  - c. **Other Deficiencies** (subparagraph 10a(3) VHA Handbook 1058.01)
  - d. **Suspensions or Terminations.** (subparagraph 10a(4) VHA Handbook 1058.01)
4. **Reports to ORO Central Office.** As soon as possible but **no later than 5 business days** after being informed of any substantive change in an MOU with an affiliate institution (or other entity) related to research laboratory security arrangements, the Medical Center Director must report the change to ORO Central Office, with a simultaneous copy to the ORO RO (Midwestern). This is also summarized in App. A, Table 2.

#### E. REPORTING RESEARCH EVENTS RELATED TO RESEARCH INFORMATION PROTECTION TO ORO

1. Investigators, RCOs, and other members of the VA research community must report the events listed in subparagraphs 10a(1), 10a(2), 10a(3), and 10a(4) VHA Handbook 1058.01 in writing to the ACOS/R&D as soon as possible, but **no later than 5 business days** after becoming aware of them.
  - b. If the RCO identifies serious or continuing noncompliance during a regulatory audit, he/she must report the noncompliance to the Medical Center Director, the ACOS/R&D, and the R&D Committee as soon as possible, but **no later than 5 business days** after becoming aware of them.
1. **Research Information Protection Incidents – Immediate Reporting. Within 1 hour** of becoming aware of any situation described in subparagraphs 11a(1) and 11a(2) VHA Handbook 1058.01, investigators, RCO and other members of the VA research community are required to ensure that the situation has been reported to the ACOS/R&D, the Medical Center Director, the JBVAMC ISO, and the JBVAMC Privacy Officer.
  - a. **Unauthorized Access.** Unauthorized access to VA sensitive information, (including unauthorized use, disclosure, transmission, removal, theft, or loss) related to research, including but not limited to protected health information, individually-identifiable private information (as defined in 38 CFR 16.102(f)(2)), and confidential information protected by HIPAA, or by Federal records requirements at 38 U.S.C. §§5701, 5705, and 7332.
  - b. **Reportable Network Security Operations Center (NSOC) Incidents.** Any research-related incident reportable to the Office of Information and Technology (OI&T) NSOC that impacts, inhibits, or compromises network security.
  - c. **Notification of Medical Center Director.** The ACOS/R&D must **immediately** notify the Medical Center Director, the R&D Committee, and any relevant research review committee upon discovering, receiving, or

otherwise becoming aware of a credible report of a research information protection incident described in items a and b above, and must ensure that the JBVAMC ISO and JBVAMC Privacy Officer have also been notified.

- d. **Written Report.** Any oral report or notification of an incident described in items a and b above must be followed as quickly as possible by a written report.

2. **Research Information Protection Incidents – Regular Reporting.** Independent of the reporting requirements described in subparagraph 11a VHA Handbook 1058.01, members of the VA research community are required to ensure that any situation described in subparagraphs 11b(1), 11b(2), and 11b(3) VHA Handbook 1058.01 has been reported in writing to the ACOS/R&D, the JBVAMC ISO, and the JBVAMC Privacy Officer **no later than 5 business days** of becoming aware of the situation,

- a. **Findings of Noncompliance.** Any findings of noncompliance related to research information security or privacy by any VA office (other than ORO) or any other Federal or state entity. Subsequent reports to ORO based on findings made by entities external to the facility must include a copy of the official findings.

- b. **Other Deficiencies.** Any other deficiency that substantively compromises the effectiveness of the facility's research information protection program.

- c. **Suspensions or Terminations.** Any suspension or termination of research (e.g., by the ACOS/R&D or other facility official) related to concerns about research information protection.

- d. **Reports to Medical Center Director.** **No later than 5 business days** of discovering, receiving a credible report of, or otherwise becoming aware of any situation described in items a, b, or c above, the ACOS/R&D must report the situation directly (without intermediaries) to the Medical Center Director, the R&D Committee, and any relevant research review committees, and must ensure that the JBVAMC ISO and JBVAMC Privacy Officer have also been notified.

- c. **Reports to ORO RO.** **No later than 5 business days** of being notified of them, the Medical Center Director must report the research information protection incidents listed in subparagraphs 11a and 11b VHA Handbook 1058.01 to the ORO RO (Midwestern), and must ensure that the JBVAMC ISO and JBVAMC Privacy Officer have also been notified.

## F. REPORTING RESEARCH EVENTS RELATED TO RESEARCH MISCONDUCT TO ORO

1. **Procedures:** The full procedures for handling research misconduct allegations are found in VHA Handbook 1058.02 (see App. A, Table 2).

2. **Notification Requirements:** ORO Central Office must be notified as soon as possible (preferably by telephone or email) of any allegation of research

misconduct. Subsequent written notification must be provided as specified by ORO Central Office.

## **REFERENCES**

**Biosafety in Microbiological and Biomedical Laboratories (5<sup>th</sup> Edition) Centers for Disease Control and Prevention and National Institutes of Health**

**Guide for the Care and Use of Laboratory Animals.** National Research Counsel, 1996.

**Public Health Service Policy on Humane Care and Use of Laboratory Animals** National Institutes of Health.

Title 5 CFR Part 334, Temporary Assignments Under the Intergovernmental Personnel Act.

Title 7 CFR Part 331, Possession, Use, and Transfer of Select Agents and Toxins

Title 9 CFR Parts 1, 2, 3, and 4. USDA Animal Welfare Act Regulations and Standards

Title 9 CFR Part 121, Possession, Use, and Transfer of Select Agents and Toxins

Title 21 CFR Part 50, Protection of Human Subjects.

Title 21 CFR Part 56, Institutional Review Boards.

Title 21 CFR Part 312, Investigational New Drug Application.

Title 21 CFR Part 812, Investigational Device Exemptions.

Title 29 CFR Part 1910, Occupational Safety and Health Standards

Title 29 CFR Part 1960, Federal Employee Occupational Safety and Health Standards.

Title 38 CFR Part 16, Protection of Human Subjects.

Title 42 CFR Part 73, Select Agents and Toxins

Title 45 CFR Part 160, Administrative Data Standards and Related Requirements: General Administrative Requirements.

Title 45 CFR Part 164, Administrative Data Standards and Related Requirements: Security and Privacy.

VA Directive 6502, VA Enterprise Privacy Program.

VA Handbook 6500, Information Security Program.

VHA Directive 1058, Responsibilities of the Office of Research Oversight

VHA Handbook 1050.01, National Patient Safety Improvement Handbook.

VHA Handbook 1058.2, Research Misconduct.

VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research.

VHA Handbook 1058.04, Debarments and Suspensions based on Research Impropriety in VA Research.

VHA Handbook 1200.1, Research and Development Committee Handbook

VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research

VHA Handbook 1200.06, Control of Hazardous Agents in VA Research Laboratories.

VHA Handbook 1200.7, Use of Animals in Research.

VHA Handbook 1200.8, Safety of Personnel Engaged in Research.

VHA Handbook 1605.1, Privacy and Release of Information.

### **FOLLOW-UP RESPONSIBILITIES**

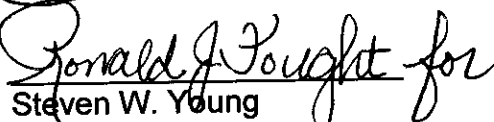
The Research Compliance Officer at the Jesse Brown VA Medical Center is responsible for updating this SOP according to the ORO recommendation(s).

**RESCISSION** This SOP dated January 26, 2011 is rescinded.

### **REVISION LOG:**

<b>Version (#, date)</b>	<b>Replaces (#, date)</b>	<b>Summary of changes</b>
v1.1date 1/26/11	v 1.0 April 30, 2009	According to revised VHA handbook 1058.01 & 1200.05.
v1.2date 4/13/11	v1.1date 1/26/11	Extensive changes made to mirror VHA Handbook 1058.01.

Approve /Disapprove

  
Steven W. Young  
Acting Medical Center Director

## Appendix A

### SUMMARY OF REQUIREMENTS FOR REPORTING RESEARCH EVENTS TO ORO

**Table 1. Reports to Office of Research Oversight (ORO) Regional Offices**

(Copy to VISN Director)* Human	Animal	Safety	Laboratory Security	Information Protection
<p>1. Problems involving risks to subjects or others that are unanticipated <u>and</u> serious <u>and</u> related to the research (e.g., work-related injuries requiring more than minor medical intervention or extended surveillance or leading to serious complications or death; interruptions related to safety, rights, or welfare of subjects or others; VA National Pharmacy Benefits Management (PBM), Data Monitoring Committee (DMC) or sponsor safety reports).</p> <p>2. Local Serious AEs (SAEs) that are unanticipated <u>and</u> serious <u>and</u> related to the research.</p> <p>3. Research Compliance Officer (RCO) audit findings of apparent serious or continuing noncompliance (also report to VISN and ORD).</p> <p>4. Institutional Review Board (IRB) findings of serious or continuing noncompliance (also report to VISN and ORD).</p> <p>5. Suspensions or terminations of study activities related to safety, rights, or welfare of subjects or others.</p>	<p>1. Unanticipated loss of animal life.</p> <p>2. Animal theft or potentially dangerous escape.</p> <p>3. Work-related or research-related injury to any person requiring more than minor medical intervention or extended surveillance or leading to serious complications or death.</p> <p>4. Reportable incidents under applicable standards, including any noncompliance or other deficiency that substantively compromises the effectiveness of the facility's animal research protection or animal research oversight programs.</p> <p>5. Suspensions or terminations of research activities related to animal safety, health, or welfare; safety, rights, or welfare of research staff or others; or operational problems necessitating research interruptions.</p>	<p>1. Work-related or research-related injury or exposure to hazardous, toxic, or infectious materials at greater than routine levels or any exposure or injury requiring more than minor medical intervention or extended surveillance or leading to serious complications or death.</p> <p>2. Reportable incidents under applicable standards, including any deficiency that substantively compromises the effectiveness of facility research safety programs.</p> <p>3. Suspensions or terminations of research activities related to the safety, rights, or welfare of research staff or others.</p> <p>4. Unauthorized laboratory decommissions or reassignments requiring identification and disposal of hazardous materials, infectious agents, or equipment.</p>	<p>1. Injury or harm to any human being or laboratory animal related to a break-in, security breach, or other security problem involving a VA research facility.</p> <p>2. Any break-in or security breach involving a VA Biosafety Level-3 (BSL-3) research laboratory.</p> <p>3. Any break-in or security breach involving a VA research facility that results in loss of any quantity of a select agent or toxin or of a highly hazardous agent, substantial damage to the facility, or substantial loss of equipment or resources.</p> <p>4. External findings of noncompliance.</p> <p>5. Any noncompliance or other deficiency that substantively compromises the effectiveness of the facility's research laboratory security program.</p> <p>6. Suspensions of terminations of research related to laboratory security concerns.</p>	<p><b>1. Report to ACOS for Research, Privacy Officer (PO), and Information Security Officer (ISO) Required Within 1 Hour:</b></p> <p>a. Unauthorized access, use, disclosure, transmission, removal, theft, or loss related to research of VA sensitive information, including protected health information, individually identifiable private information, or confidential information, by the Privacy Act, HIPAA, or by Federal records requirements.</p> <p>b. Any research-related incidents reportable to NSOC.</p> <p><b>2. Report to ACOS for Research, PO, and ISO Required Within 5 Business days:</b></p> <p>a. Findings of noncompliance.</p> <p>b. Any other deficiency that substantively compromises the effectiveness of the facility's research information protection program.</p> <p>c. Suspensions of terminations of research related to information protection concerns.</p>

***NOTE:** Except as noted under Information Protection Item 1, members of the VA research community, including RCOs, must ensure that the relevant research review committees are notified within 5 business days after becoming aware of these events. The facility Director must notify ORO in writing within 5 business days after being informed of these events.*

**DECISION CHARTS FOR REPORTING RESEARCH EVENTS ARE AVAILABLE ON THE ORO WEBSITE**

**Appendix A**

**SUMMARY OF REQUIREMENTS FOR REPORTING RESEARCH EVENTS TO ORO**  
**Table 2. Reports to ORO Central Office**

<b>(Copies to ORO Regional Office and VISN Director) * Human</b>	<b>Animal</b>	<b>Safety</b>	<b>Laboratory Security</b>	<b>Information Protection</b>
<p>1. Any proposed change in the facility's Federalwide Assurance (FWA) or other ORO-approved Assurance,</p> <p>2. Any proposed change in the facility's designated IRB(s).</p> <p>3. Any substantive change in an Memorandum of Understanding (MOU) related to the designation of IRBs or other human research protection arrangements.</p> <p>4. Failure of the VA facility to achieve "full accreditation" status from the VA human research accreditation organization, any change in the facility's accreditation status, or any change in the accreditation status of an affiliate involved in the facility's human research protection program.</p>	<p>1. Any change in the facility's Public Health Service (PHS) Animal Welfare Assurance as filed with the Office of Laboratory Animal Welfare (OLAW).</p> <p>2. Any change in the status of the PHS Animal Welfare Assurance of an affiliate or other entity on which the facility relies.</p> <p>3. Any new MOU or substantive change in an MOU related to laboratory animal welfare or animal care and use arrangements</p> <p>4. Failure of the VA facility to achieve "full accreditation" status from the VA animal research accreditation organization, any change in the facility's accreditation status, or any change in the accreditation status of an affiliate involved in the facility's animal care and use program.</p>	<p>1. Any substantive change in an MOU related to research safety arrangements.</p>	<p>1. Any substantive change in an MOU related to research laboratory security arrangements.</p>	<p>Not Applicable</p>

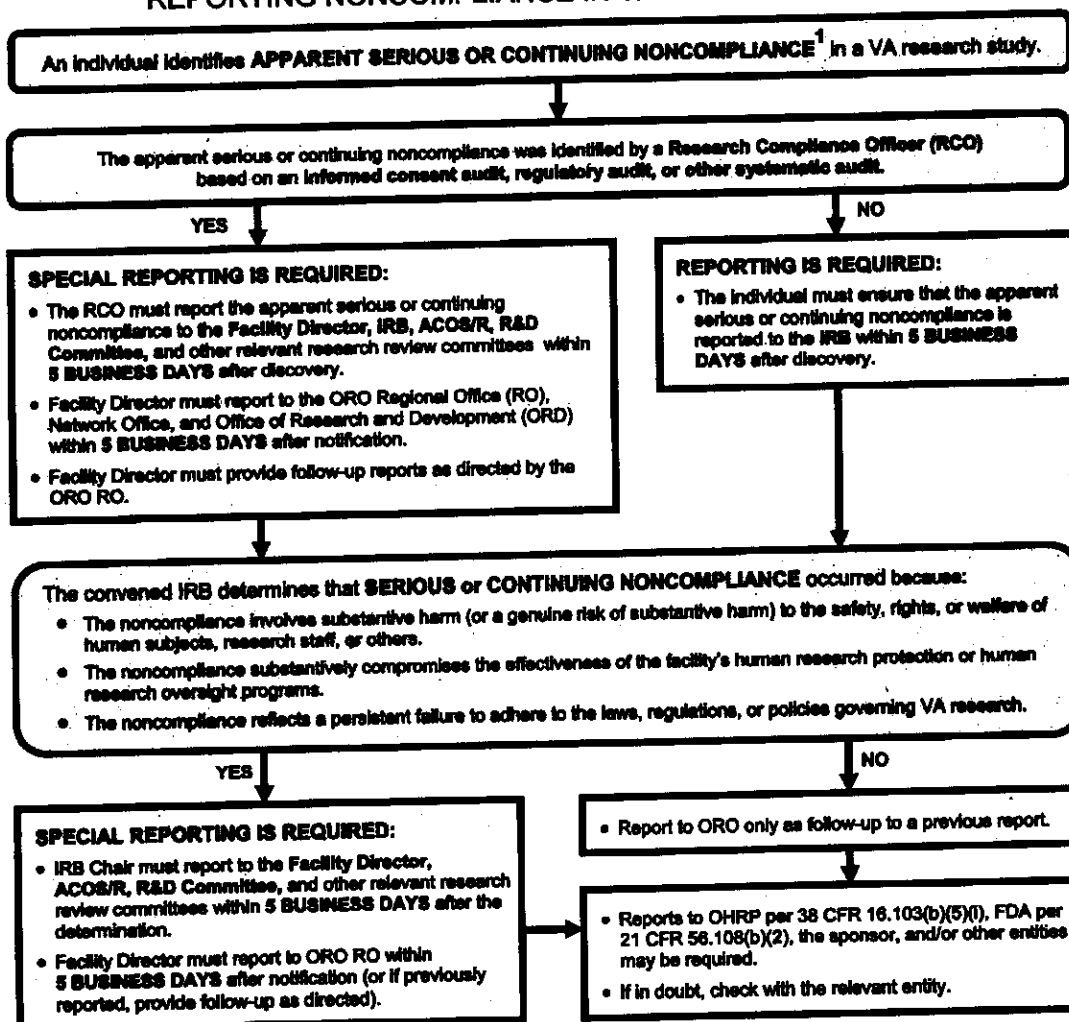
*\* NOTE: The facility Director must notify ORO in writing within 5 business days after being informed of these events.*

**SUMMARY OF REQUIREMENTS FOR REPORTING RESEARCH EVENTS TO ORO**  
**Table 3. Notification to ORO Central Office – Research Misconduct\***

<b>Research Misconduct</b>
<p>Notify ORO Central Office as soon as possible (preferably by telephone or email) about any allegation of research misconduct. Subsequent written notification must be provided as specified by ORO Central Office.</p> <p>2. Notification needs to include whether or not the allegation involves any of the following:</p> <p>Harm or threat of harm to research subjects.</p> <p>Harm or threat of harm to those involved in an inquiry or investigation.</p> <p>(c) Serious violations of animal welfare requirements.</p> <p>(d) Research safety or security compromises.</p> <p>(e) Risks to public health or safety.</p> <p>(f) Loss or destruction of VA funds or property.</p> <p>(g) Possible violations of civil or criminal law.</p> <p>3. Notify ORO Central Office of the following related to any research misconduct proceeding:</p> <p>(a) Opening of a research misconduct <u>inquiry</u>.</p> <p>(b) Requests for changes or departures from VHA Handbook 1058.2 (ORO approval required).</p> <p>(c) Extensions of the inquiry review period (ORO approval required).</p> <p>(d) Closure of a research misconduct <u>inquiry</u> without further investigation (include Inquiry Report and the concurrence of facility Director).</p> <p>(e) Opening of a research misconduct <u>investigation</u>.</p> <p>(f) Extensions of the investigation review period (ORO approval required).</p> <p>(g) Closure of a research misconduct <u>investigation</u> (include Investigation Report and recommendations of facility Director).</p> <p>(h) Decision of the Veterans Integrated Service Network (VISN) Director.</p>

***NOTE:** Consult ORO's Web site at: [www1.va.gov/oro/](http://www1.va.gov/oro/) and VHA Handbook 1058.2 for complete reporting requirements and procedures related to allegations of research misconduct.*

## REPORTING NONCOMPLIANCE IN VA HUMAN RESEARCH

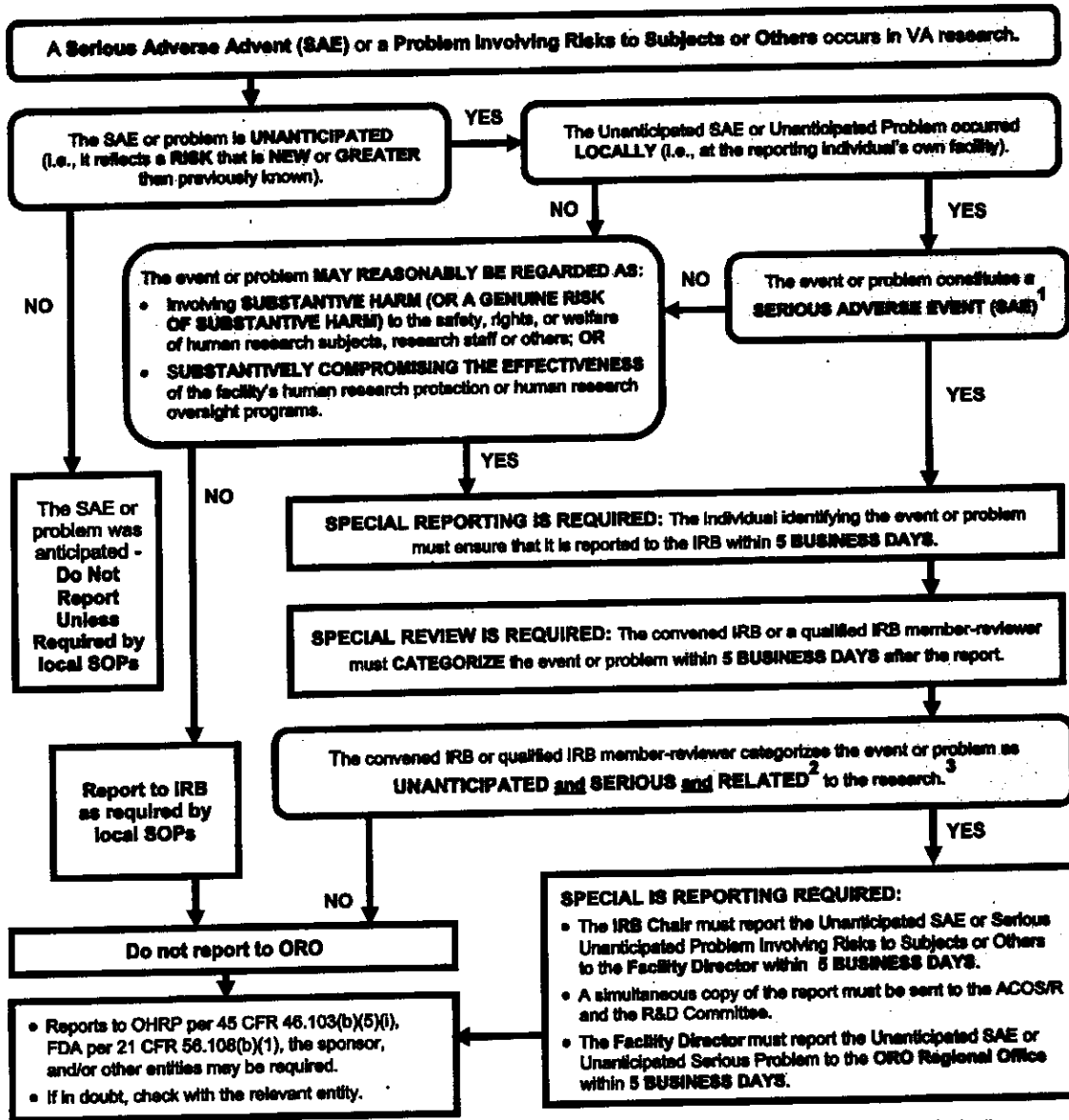


<sup>1</sup> See 38 CFR 16.103(b)(5)(i), 21 CFR 56.108(b)(2), and VHA Handbook 1058.01 §6. Examples considered by VA to reflect apparent serious or continuing noncompliance that must be reported to the IRB within 5 business days include, but are not limited to:

- External findings of noncompliance by any VA office or other Federal or State oversight agency
- Initiation of VA research without written notification from the ACOS/R, without IRB approval, or prior to obtaining required informed consent
- Lack of a required, signed informed consent document or required, signed HIPAA Privacy Rule authorization for one or more subjects
- Use for one or more subjects of an informed consent document whose content was not approved by the IRB
- Failure to report one or more unanticipated SAEs or serious unanticipated problems involving risks to subjects or others as required
- Conduct of research by one or more persons without the required credentialing, privileging, or scope of practice or outside the approved scope of practice.
- Continuation of interactions or interventions with human subjects beyond the specified approval period
- Implementation of substantive protocol changes without IRB approval, except to prevent immediate hazard to a subject
- Failure to obtain CRADO approval for VA research involving prisoners or children or for International VA research
- Serious programmatic noncompliance, eg, conduct of IRB business by an improperly constituted IRB or with less than a quorum of voting members, improper designation of research as exempt, noncompliant approval or noncompliant documentation by the IRB of an informed consent waiver, documentation waiver, or HIPAA authorization waiver, failure to provide for PO and ISO review of proposed research
- Failure to implement IRB-required changes within the IRB-specified time period
- Deficiencies in informed consent or HIPAA authorization procedures or documentation for 10 or more subjects
- Failure to maintain documentation required by the IRB or the IRB-approved protocol
- Failure to implement remedial actions within the time periods specified by VA policy without acceptable justification

[ORO: 05/26/2010]

## REPORTING SERIOUS ADVERSE EVENTS (SAEs) AND PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS IN VA RESEARCH



<sup>1</sup> An SAE is an untoward physical or psychological occurrence in human subject participating in research that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect, or that requires medical, surgical, behavioral, social, or other intervention to prevent such an outcome [VHA Handbook 1058.01 §§4b & 4w].

<sup>2</sup> "Related" means the event or problem may reasonably be regarded as caused by, or as probably caused by, the research [VHA Handbook 1058.01 §4p].

<sup>3</sup> The convened IRB or qualified IRB member-reviewer must also document whether or not action is needed to prevent an immediate hazard to subjects. If consent or protocol modifications are required, the convened IRB must determine whether previously enrolled subjects must be notified, and if so, when and how notification must occur and be documented [VHA Handbook 1058.01 §6d].

[ORO: 05.26.2010]